510(k) Summary for the
Dimension Vista™ System Chemistry 1 Calibrator
(CHEM 1 CAL – KC110)

AUG 2 1 2006

A. 510(k) Number: K061838

B. Analytes: Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), **Blood Urea Nitrogen (BUN)**[1] and Uric Acid (URCA).

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Chemistry 1 Calibrator
(CHEM 1 CAL – KC110)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry

G. Intended Use: The CHEM 1 CAL is an *in vitro* diagnostic product for the calibration of Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), **Blood Urea Nitrogen (BUN)**[1] and Uric Acid (URCA) methods on the Dimension Vista™ System.

H. Device Description:

CHEM 1 CAL is a liquid, multi-analyte, bovine serum albumin based product containing calcium, cholesterol, creatinine, glucose,

[1] The Dimension Vista™ System Chemistry 1 Calibrator was previously cleared for the calibration of blood urea nitrogen (BUN) in the Dimension Vista™ System under K051087.

lactic acid, magnesium, thyroxine, urea nitrogen and uric acid. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 2.5 mL. This same product, the Dimension Vista™ System Chemistry 1 Calibrator (KC110), was previously cleared (K051087) for the calibration of the Blood Urea Nitrogen (BUN) method on the Dimension Vista™ system.

I. Substantial Equivalence Information:

	Device	Predicate Devices				
Item	**Dimension Vista™ System Chemistry 1 Calibrator[2]**	**CHEM I Calibrator K860021 (URCA–K862359)**	**Chemistry II Calibrator K861700**	**Cholesterol Calibrator K861700**	**Thyroxine Calibrator K862359**	**Thyronine Uptake Calibrator K862359**
Intended Use	The CHEM 1 CAL is an *in vitro* diagnostic product for the calibration of Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), **Blood Urea Nitrogen (BUN)[2]** and Uric Acid (URCA) methods on the Dimension Vista™ System.	The Dimension® Chemistry I Calibrator is an *in vitro* diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Calcium (CA), Creatinine (CREA), Glucose (GLU/GLUC), Lactic Acid (LA), Urea Nitrogen (BUN) and Uric Acid (URCA) methods.	CHEM II Calibrator is an *in vitro* diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the magnesium (MG), phosphorus (PHOS) and triglycerides (TRIG) methods.	The Dimension® Cholesterol Calibrator is an *in vitro* diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Cholesterol (CHOL) method.	The Dimension® Thyroxine Calibrator is an *in vitro* diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Thyroxine (T4) method.	The Dimension® Thyronine Uptake is an *in vitro* diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Thyronine Uptake method.
Analytes	Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), **Blood Urea Nitrogen (BUN)[2]** and Uric Acid (URCA)	Calcium (CA), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Urea Nitrogen (BUN) and Uric Acid (URCA).	Magnesium (MG).	Cholesterol (CHOL).	Thyroxyne (T4).	Thyronine Uptake (TU).

[2] The Dimension Vista™ System Chemistry 1 Calibrator was previously cleared for the calibration of blood urea nitrogen (BUN) in the Dimension Vista™ System under K051087.

	Device	Predicate Devices				
Item	**Dimension Vista™ System Chemistry 1 Calibrator[2]**	**CHEM I Calibrator K860021 (URCA–K862359)**	**Chemistry II Calibrator K861700**	**Cholesterol Calibrator K861700**	**Thyroxine Calibrator K862359**	**Thyronine Uptake Calibrator K862359**
Form	Liquid.	Lyophilized.	Liquid.	Lyophilized.	Lyophilized.	Lyophilized.
Traceability	**BUN – NIST SRM 912[2]** CA – NIST SRM 915. CHOL – Abell-Kendall (CDC-NCEP). CREA – NIST SRM 914. GLU – NIST SRM 917. LA – Lactic acid –lithium salt A-Grade. MG – NIST SRM 929A. T4 – USP. TU – Calculated value. URCA – NIST SRM 913.	BUN – NIST SRM 912 CA - NIST SRM 915. CREA - NIST SRM 914. GLU - NIST SRM 917. LA - Lactic acid – lithium salt A-Grade. URCA - NIST SRM 913.	MG - NIST SRM 929A.	CHOL – NIST SRM 911.	T4 – Thyroxine Master Pool.	TU – Thyronine Uptake Master Pool.
Matrix	Bovine serum albumin based product.	Bovine serum albumin based product.	Pure magnesium dissolved in a dilute solution of HCL, reagent grade potassium dihydrogen phosphate and reagent grade glycerol.	Bovine serum albumin based product.	Human serum based product.	Human serum based product.
Number of Levels	Two levels.	Three levels.	Three levels.	Three levels.	Five levels.	Five levels.

[2] The Dimension Vista™ System Chemistry 1 Calibrator was previously cleared for the calibration of blood urea nitrogen (BUN) in the Dimension Vista™ System under K051087.

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
   Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
   ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Target shelf life for the Dimension Vista™ Chemistry 1 Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined where the allowable shelf life percent change should be less than or equal to:

Analyte	Allowable Shelf life percent change
Urea Nitrogen[3]	≤ 5%.
Calcium	≤ 5 %
Cholesterol	≤ 3%
Creatinine	≤ 5%
Glucose	≤ 5%
Lactic Acid	≤ 5%
Magnesium	≤ 3%
Thyroxine	≤ 6%
Thyroxine Uptake	≤ 6%
Uric Acid	≤ 5%

Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial punctured by the instrument and stored on board has a stability claim of one day.
An open vial not on instrument, but recapped and stored in a refrigerator has a stability claim of 30 days.

For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are

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recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 0, 8 hrs, 2, 8, 31 versus freshly opened vials.

2. Traceability: The assigned values of the Chemistry 1 Calibrator are standardized to the enclosed table of assigned values:

Constituent	Traceability
BUN[4]	NIST SRM[a] 912
CA	NIST SRM 915
CHOL	NIST SRM 911 (CDC[b]) Abell-Kendall reference method
CREA	NIST SRM 914
GLU	NIST SRM 917
LA	Lactic acid- lithium salt (A- Grade)
MG	NIST SRM 929 A
T4	USP[c]
TU	Calculated value
URCA	NIST SRM 913

[a] National Institute of Standards and Technology – Standard Reference Material.
[b] Centers for Disease Control.
[c] United States Pharmacopeia.

3. Bottle Value Assignment:

Urea Nitrogen, calcium carbonate, creatinine, cholesterol, glucose, lactic acid, magnesium gluconate, uric acid, and thyroxine reference materials are weighed appropriate aqueous solutions or human serum traced to primary standard material. Master Pool and standards are stored frozen for each analyte. The verification of the Master Pool/Standard values are compared against previously approved Master Pool/Standard values.
The stock solution is made by adding reference materials gravimetrically to stock solution at target concentrations. The stock solution values are verified versus previously approved Master Pool/Standard values.
The commercial lot is made by adding calculated quantities of stock solution to base matrix in appropriate concentrations for two calibrator levels. The concentration of each level is verified by using an instrument calibrated with Master Pools.
The final bottle values for each level of the commercial lot is assigned and verified using multiple instruments by testing N = 45 replicates.

[4] The Dimension Vista™ System Chemistry 1 Calibrator was previously cleared for the calibration of blood urea nitrogen (BUN) in the Dimension Vista™ System under K051087.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor M. Carrio
RA/QS Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714-6101

AUG 2 1 2006

Re: k061838
Trade/Device Name: Dimension Vista™ Chemistry 1 Calibrator (KC110)
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: June 28, 2006
Received: June 29, 2006

Dear: Mr. Carrio

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K061838

Device Name:

Dimension Vista™ Chemistry 1 Calibrator (KC110)

Indications for Use:

The CHEM 1 CAL is an *in vitro* diagnostic product for the calibration of Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), Blood Urea Nitrogen (BUN), and Uric Acid (URCA) methods on the Dimension Vista™ System

Prescription Use X **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K061838